UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,842	05/04/2005	Ian Clarke	P/3653-12	6092

2352 7590 07/02/2010

OSTROLENK FABER GERB & SOFFEN
1180 AVENUE OF THE AMERICAS
NEW YORK, NY 100368403

EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
07/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/533,842
Filing Date: May 04, 2005
Appellant(s): CLARKE ET AL.

Robert C. Faber
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/15/10 appealing from the Office action mailed 8/18/09.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1, 2, 4, 7, 9-11, 15, and 19-21 are currently pending and rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

CA 2,083,555	LAING	5-1994
GB 2,165,312	KEIME	4-1986
US 4,666,430	BROWN	5-1987

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2, 4, 7, 9-11, 15, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laing (CA 2,083,555) in view of Keime (GB 2,165,312).

3. With respect to Claims 1, 2, and 4, Laing discloses an apparatus 10 for controlled dispensing of a liquid from a flexible bag 40 comprising a substantially gas-tight chamber 20 adapted to contain the flexible bag 40, and an outlet (48 and 49) adapted to receive an outlet conduit 45 communicating with the flexible bag 40. A source of gas 58

is arranged to release gas into the chamber 20, applying pressure to the exterior walls of the flexible bag 40, and a pressure regulator 50 is operable to self-regulate the pressure applied to the bag throughout the dispensing process, thus causing fluid to be dispensed from the bag in a controlled manner. The pressure regulator 50 comprises a microprocessor 56, an air pump 58, and a transducer 55. Regarding Claim 2, the air bag portion 30 of the chamber 20 is substantially air tight. The outlet (48 and 49) comprises a clamp 28 and a needle 29 adapted to seal the chamber (Page 11, Lines 3-26), and the gas supply 58 is operable to supply gas under pressure to the interior of the chamber 20. The liquid outlet from the chamber is sealed to the outlet conduit in a way that effectively prevents liquid from leaking outside of the conduit. The pressure regulator 50, which comprises air pump 58, microprocessor 56, and pressure transducer 55, is arranged to regulate the flow of gas from the source to the chamber (Page 12, Lines 15-20). Laing, however, does not specifically disclose that the pressure regulator self-regulates the pressure based on pressure feedback from the *gas* in the chamber (Laing uses pressure feedback from the liquid instead).

Keime discloses a portable injector comprising a compressed gas source 18 that injects gas into a substantially gas-tight chamber to initiate fluid flow. The device further comprises a pressure regulator 23 and pressure relief valve 22 that are capable of controlling the air pressure in the chamber. The pressure regulator is disposed at the inlet to the chamber, between the gas source and the flexible bag, and regulates the pressure in the chamber *based on the pressure within the chamber*. Although the desired pressure is initially overshot by about 10 millibars, it is quickly stabilized to the

desired pressure shortly thereafter. Although the regulator 23 is adapted for manual control, it is fully capable of being used to regulate the pressure within the chamber, and Keime clearly suggests that maintaining a specific gas pressure within the chamber is the ultimate goal of the regulator (see Page 2, Lines 30-85). The automation of a manual activity does not constitute a patentable improvement over the prior art. See MPEP § 2144.04 [Section III]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Laing with the pressure regulator and pressure relief valve of Keime in order to provide an alternate means for regulating the air pressure within the chamber based on the current gas pressure within the chamber.

4. With respect to Claims 4 and 19, Laing further discloses that the source of gas 58 is connected to an inflatable bladder 30 such that the inflatable bladder is in contact with at least a portion of the exterior wall of the air bag 40. See Figure 1. Regarding claim 19, the pressure regulator is operable to regulate the flow of gas from the source into the inflatable bladder (Page 7, Lines 14-26).

5. With respect to Claim 7, Laing discloses that the inflatable bladder 30 comprises an inflatable sock positioned and operable to wrap around at least a portion of the flexible bag 40 (see Figure 1). An “inflatable sock” is interpreted by the examiner as being any type of bag that is capable of being filled with air.

6. With respect to Claims 10 and 11, Laing discloses that the source of gas is a reservoir 35 pressurized by a pump 58 (see Figure 1). The pump 58 is controlled by the

microprocessor 56 in order to change the pressure in the inflatable bladder, thus controlling the flow rate of fluid from the flexible medical supply bag.

7. With respect to Claim 20, Laing discloses that the apparatus comprises a first chamber 10 comprising a flexible bag and a second chamber (50, 52) comprising the source of gas (air pump 58) and the pressure regulator 50.

8. With respect to Claim 9, Laing discloses the portable injector of claim 1 (see rejection above) wherein air is pumped into the chamber 30 by pump 58. Laing does not disclose that the source of gas comprises a pressure vessel of precompressed gas. Keime discloses a portable injector comprising a compressed gas source 18 that injects gas into a chamber to initiate fluid flow. The device further comprises a pressure regulator 23 that is capable of controlling the amount of air infused into the chamber, thus controlling fluid flow. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the portable injector of Laing with the pressurized gas source of Keime in order to provide an alternate means for pressurizing the chamber to create fluid flow from the bag. The use of pressurized gas sources to pressurize a chamber is well established in the art of fluid flow.

9. With respect to Claim 15, Laing discloses the portable injector of Claim 1 and that the chamber 10 has a depth significantly less than the length and width of the chamber (see Figure 1). Laing, however, does not disclose that the pressure vessel and pressure regulator are located alongside the chamber in a common housing.

Keime discloses a portable injector wherein the pressure vessel 18 and pressure regulator (21, 23) are located alongside the chamber 4 in a common housing arranged in a cuboidal configuration such that the pressure vessel and pressure regulator are contained within the depth of the housing (see Figures 1 and 2). Repositioning the pressure vessel and regulator within the chamber housing will improve the portability of the device. Additionally, integration of components and changes of shape are mere obvious matters of engineering choice and do not represent a patentable improvement over the prior art. See MPEP § 2144.04.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laing in view of Keime, and further in view of Brown (US 4,666,430). Laing and Keime reasonably suggest the device substantially as claimed, but do not specifically teach that the pressure regulator comprises a compression spring-controlled piston having a needle valve. Brown teaches a device for delivering a constant gas pressure from a compressed gas source 12 to a destination. The device is controlled by a pressure regulator comprising a compression spring-controlled piston that only allows gas to flow when a specific amount of pressure is applied to the piston (see Figures 5 and 6). The constant pressure applied by the gas source 12 acts on a compressible fluid source to urge the fluid source out of its container at a constant rate (see abstract and Column 2, Line 45 through Column 3, Line 13). This type of valve is well known in the art as a means for applying a constant pressure to a fluid source, thereby providing constant fluid flow. Furthermore, the use of needle valves is extremely common in the art

because they provide a cost-effective means for providing a fluid-tight connection between two flow paths (see Pauliukonis (US 4,033,378), or any other typical needle valve as is known in the art). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid delivery device of Laing and Keime with the pressure regulator of Brown in order to provide a well known, alternate means for providing a constant pressure to a chamber, thereby providing a constant liquid flow out of the bag.

(10) Response to Argument

Appellant's arguments filed 4/15/10 have been fully considered but they are not persuasive.

First, appellant argues that Laing does not teach the following (see the top of page 5 of the appeal brief):

1. The pressure supplied from the pump is continuously maintained at a constant and predetermined level.

2. The pressure applied to the flexible bag is continuously maintained at a constant and predetermined level.

In response, it is the examiner's position that these conditions are substantially THE SAME (any air that is pumped by the injector will be evenly dispersed throughout the bag, as per Pascal's Law). The pressure that is applied from the air supply will substantially be equal to the pressure within the chamber, which in turn will be the same

as the pressure that it applied to the bag. Laing teaches that air pressure within the chamber is maintained at a constant level by means of a pressure regulator 50 (i.e. within an upper and lower threshold), such that fluid flow is controlled. This function meets appellant's claim language that pressure is supplied and maintained at a constant and predetermined level.

Second, appellant states that Laing cannot achieve the same accuracy results as the instant device (see the middle of Page 5 of the brief, as well as the affidavit filed 7/30/10). However, Laing clearly maintains a desired pressure within a predetermined threshold range. Therefore, Laing's pressure is substantially constant. No device can maintain a perfectly constant pressure, so even applicant's device has a threshold range. It is important to note that *there are no claimed structural elements that differentiate Laing's threshold pressure control from the instant invention* (with the exception of the use of air pressure feedback instead of fluid pressure feedback, which is addressed by Keime).

Third, appellant argues that Laing's device does not maintain a constant pressure within the chamber because the contact area between the inflatable bladder 30 and the fluid bag 40 changes as the fluid bag empties (bottom of page 5 through middle of page 6). This is simply not true. Laing and Keime clearly suggest applying air at a CONSTANT PRESSURE. This will cause the inflatable bladder 30 to press against the fluid bag 40 and at a pressure that is identical to the pressure within the bag. Because

pressure is a per-unit-area measurement, increasing the contact area between the inflatable bladder 30 and fluid bag 40 will *merely apply the same pressure on a larger area of the bag*. This meets the limitations of claim 1, specifically that the *pressure applied to the flexible bag is continuously maintained at a constant and predetermined level.*

The surface area at which pressure applies has nothing to do with whether or not a constant pressure is applied to the bag by the inflatable bladder 30. Since Pressure=Force/Area (not P=F*A, as stated by applicant), increasing the total force applied while simultaneously increasing the area upon which that force is applied **will not change the pressure**)

Applicant does not claim that a constant pressure is applied *over a constant area* of the bag (or that a constant force is applied). *Applicant merely claims that the pressure applied to the flexible bag by the inflatable bladder is continuously maintained at a constant and predetermined level (i.e. the pressure within the inflatable bladder remains substantially constant).*

Fourth, appellant argues that a combination of Laing's pressure transfer system with Keime's pressure regulator will not produce constant infusion (bottom of page 6). Specifically, appellant states that "instead, if gas pressure (i.e. the force applied to the bag) is held constant, such combination will gradually increase an hourly output rate [...] as the surface contact area between the saline bag and surrounding surfaces increases during the process" (page 6, paragraph 3). However, Keime clearly suggests that

maintaining a specific gas pressure within the chamber is the ultimate goal of the regulator (see Page 2, Lines 30-85), and therefore suggests that maintaining constant air pressure would be a viable alternate means for providing controlled flow rate of fluid. **More importantly, appellant's claim says nothing of a constant fluid output rate.** Appellant merely claims that the pressure supplied from the pump is continuously maintained at a constant and predetermined level, and that the pressure applied to the flexible bag is continuously maintained at a constant and predetermined level. **Laing and Keime reasonably suggest both of these claimed features, and teach devices that offer *controlled* fluid output (not necessarily constant).**

Fifth, appellant argues that Keime's inflatable bladder 30 is not an inflatable sock that wraps around at least part of the fluid bag. This is clearly not true. **In Figure 1, Laing teaches that the inflatable bladder is an inflatable sock 30 that has a flexible outer wall, said outer wall contacting and partially wrapping around the fluid bag 40**. However, Applicant conveniently points to Figure 3, which is a completely different embodiment of Laing's invention wherein a plate is disposed between the inflatable bladder and the fluid bag.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Philip R Wiest/

Examiner, Art Unit 3761

Conferees:

/Leslie R. Deak/

Primary Examiner, Art Unit 3761